

DEC 19 2003

**Wallace (Sure View™) Embryo Replacement Catheters &
Trial Transfer Catheters.
510(K) Notification**

K033084

SECTION 5.0 : 510K SUMMARY

DATE SUBMITTED: 27 August 2003

SUBMITTER: Portex Ltd
Hythe
Kent
England, CT21 6JL

CONTACT PERSON: Mr Steve Ogilvie,
Regulatory and Scientific Affairs Director,
Portex Ltd,
Military Road,
Hythe, Kent, England, CT21 6DB
Phone 00 44 (0)1303 208011
Fax 00 44 (0)1303 262798

DEVICE NAME: Wallace (Sure View™) Embryo Replacement Catheter
& Trial Transfer Catheter.

COMMON NAME AND CLASSIFICATION: Ultra sound visible embryo transfer catheter
Class II MQF, 21 CFR 884.6110

PREDICATE DEVICES:

- Predicate 1: Wallace Embryo Transfer Catheter range 18-23cm already marketed in the USA under K990350
- Predicate 2: Wallace Trial Transfer Catheter range 18-23cm already marketed in the USA under K990348
- Predicate 3: Cook Echotip® Soft-Pass Embryo Transfer Catheter already marketed in the USA under K983594

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DEVICE DESCRIPTION:

Embryo Replacement Catheters

The Embryo Replacement Catheters (for use in ultrasound-guided transfers) are single use devices for the introduction of embryos into the uterine cavity following in-vitro fertilisation.

The devices have overall lengths; 18cm (CE 118A) and 23cm (CE 123A) and consist of a soft, flexible inner cannula, with end opening, and a detachable outer sheath that is attached to the inner catheter by a Luer taper. The inner catheter is of dimensions 1.5mm (OD) x 0.76 mm(ID) with a lumen that is uniform throughout its length, with a series of 1cm graduations at the proximal end. The inner catheter protrudes from the outer sheath by 5cm and the outer sheath has a series of 1cm graduations at the distal end.

Trial Transfer Catheters.

The Trial Transfer Catheters (for use in ultrasound-guided transfers) are single use devices used to assess the passage through the cervix prior to embryo transfer.

The devices have overall lengths; 18cm (CE 418A) and 23cm(CE 423A) and consist of a flexible inner cannula, with blind end, and a detachable outer sheath that is attached to the inner catheter by a Luer taper. The inner catheter is of dimensions 1.5mm (OD) x 0.76 mm(ID) with a series of graduations at the proximal end. The inner catheter protrudes from the outer sheath by 5cm and the outer sheath has a series of 1cm graduations at the distal end.

TECHNOLOGICAL CHARACTERISTICS OF PROPOSED VERSUS PREDICATE DEVICES:

The proposed devices are substantially equivalent to Predicate devices 1 & 2 -Wallace Embryo Transfer Catheter (K990350) & Wallace Trial Transfer Catheter (K990348) in all the following aspects:

- **Tip protector.** The tip protector for the proposed devices 1 & 2 is identical in material composition to that of Predicate 1 & 2.
- **Outer sheath.** The outer sheath for the proposed devices 1 & 2 is identical in material composition and profile to that of Predicate 1 & 2.
- **The print markings.** The print ink for the proposed devices 1 & 2 is identical in composition to the ink used for Predicate 1 & 2. The print layout for the proposed device displays identical information as the layout on Predicate 1 & 2.
- **Outer and inner hub.** The material composition for the outer and inner hub is identical for both the proposed devices 1 & 2 and Predicate 1 & 2.
- **Inner catheter.** The proposed devices are made from the same materials as Predicate 1 & 2, with the exception that the material is modified to enhance the visibility of the catheter under ultrasound. In this respect, the inner catheter is substantially equivalent to Predicate 3.



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PERFORMANCE / CLINICAL DATA:

Comparison of the performance of the proposed device with the predicate confirms substantial equivalence in all aspects.

CONCLUSION:

Comparison of the proposed device to the predicate devices supports the conclusion that the proposed device is substantially equivalent to existing legally marketed devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2003

Mr. Barry Smith
Regulatory Affairs Manager
Portex, Ltd.
Boundary Road, Hythe
Kent CT21 6JL
UNITED KINGDOM

Re: K033084
Trade/Device Name: Wallace (Sure View™) Embryo
Replacement Catheter and Trial Transfer Catheter
Regulation Number: 21 CFR 884.6110
Regulation Name: Assisted reproduction catheter
Regulatory Class: II
Product Code: 85 MQF
Dated: August 27, 2003
Received: September 30, 2003

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

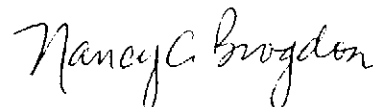
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Wallace (Sure View TM) Embryo Replacement Catheters &
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SECTION 4.0: STATEMENT OF INDICATION FOR USE

510(K) Number (if known): K033084

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DEVICE NAME:

Wallace (Sure View TM) Embryo Replacement Catheters & Trial Transfer Catheters.

INDICATIONS FOR USE:

Embryo Replacement Catheters are sterile, single-use devices for ultrasound guided introduction of embryos into the uterine cavity following in vitro fertilisation.

Trial Transfer Catheters are sterile, single-use devices for determining whether the cervix is passable for a Wallace embryo replacement catheter

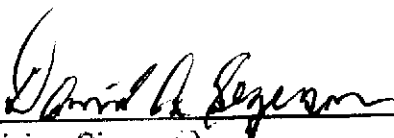
Prescription Use YES
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Director)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033084